REMARKS

The Pending Claims

Before entry of the preceding amendments, Claims 96-138 are pending in this application. The application contains claims related to methods and compositions. With respect to claims directed to methods, Claims 109-113 are directed to a method of delaying gastric emptying and promoting absorption of an active ingredient to be absorbed through the stomach. Claims 128-136 relate to a method of delaying gastric emptying and prolonging small intestine transit time while promoting an anti-atherogenic and/or anti-diarrheal effect and/or promoting digestion, dissolution and/or absorption of an active ingredient.

With respect to compositions of matter, Claims 96 - 108 are directed to absorption promoting and/or gastric emptying slowing compositions. Claims 114-127, 137 and 138 are directed to anti-atherogenic, anti-diarrheal, digestion, dissolution and/or absorption promoting and/or gastrointestinal transit slowing and/or gastric emptying slowing compositions. The Examiner has withdrawn Claims 131-136 from consideration.

The Office Action

The Examiner acknowledged receipt of Applicant's extension of time, Response to Office Action, and Terminal Disclaimer filed 01/02/03 (which Applicant mailed December 26, 2002.

The Examiner stated that the terminal disclaimer filed on 01/02/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 5,977,175 has been reviewed and is accepted. The terminal disclaimer has been recorded.

No claims were allowed.

The Examiner rejected Claims 96-130, 137, and 138 on the following grounds.

A. Rejections under 35 U.S.C. § 102

The Examiner rejected Claims 96, 98-106, 114, 116, 117, and 119-125, as being anticipated by U.S. Patent No. 4,572,833 granted to Pedersen *et al.*, because:

> **. . . Claims 96, 98-106, 114, 116, 117, and 119-125 are rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen et al. US 4,572,833. Pedersen teaches controlled release composition comprising multiple-unit of active substance being coated with hydrophobic layer (abstract and column 3). The hydrophobic material can be selected from oils, waxes, fats, including higher fatty acids, and mixtures thereof (column 4). Active substance, dosage forms and coating agent are disclosed in columns 6-8.**

A claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. *Verdgaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicant has amended Claims 96 and 114 to recite, *inter alia*, ". . . a first component comprising an active ingredient . . . ; and a second component comprising a *carrier-dispersed* form of an active lipid . . . *having a molecular structure similar to a hydrolyzed end-product of fat digestion*, and . . . " The addition of the word "and" between the recitations of the first and second components in Claims 96 and 114, the insertion of a colon at the end of line 2 of Claim 96, and the insertion of a hyphen between the words "carrier" and "dispersed" in line 6 of Claim 114, are merely formal refinements of those claims. The amendments to Claims 96 and 114 to recite the term "carrier-dispersed" instead of the former expression "carrier-dispersible" is supported in the specification, as originally filed, for example, at page 13, lines 7-8, where it is stated, "The active lipids suitable for use with this invention are employed in well *dispersed* form in a pharmaceutically acceptable carrier." (Emphasis added). The recitation in amended independent Claims 96 and 114 of the active lipid "*having a molecular structure similar to a hydrolyzed end-product of fat digestion*, is supported in the specification, e.g., at page 12, lines 10-12. The specification clarifies that "[e]xamples of hydrolyzed end products are molecules such as glycerol and fatty acids." (Specification at page 12, lines 12-13). In addition, Claims 96 and 114 are amended to recite that the active lipid is "in an amount that can trigger the jejunal brake reflex,"

which is supported by the disclosures of the specification as originally filed, for example at page 4, lines 3-6; and especially page 14, lines 15-19. Claims 96 and 114 are also amended to recite that the active lipid is ". . . selected from the group consisting of: (A) saturated and unsaturated *fatty acids,"* which amendment from the recitation of "fats" is supported in the specification, e.g., at page 12, lines 14-15.

Applicant believes that the basis of rejection is overcome, because Pedersen *et al.* fails to teach all of the elements of amended Claims 96, 114, and the other subject claims.

As Applicant has previously noted, the specification specifically defines the term "active lipid" to encompass "a digested or substantially digested molecule having a structure and function substantially similar to a hydrolyzed end-product of fat digestion. Examples of hydrolyzed end products are molecules such as glycerol and fatty acids." (Specification at page 12, lines 10-13). These "end-products" of fat digestion include only fully hydrolyzed fats, such as fatty acids and glycerol, which would not include lipids in every form in which they occur. The desired intestinal slowing response (e.g., the "jejunal brake"), which facilitates the absorption promoting and/or gastric emptying slowing properties of the claimed composition, is "jump-started" by delivering the claimed compositions comprising end products of digestion, rather than waiting for the normal process of digestion to make available the trigger for the slowing of intestinal transit, rather than waiting for the normal process of digestion to make available the trigger for the slowing of intestinal transit (and thereby delaying gastric emptying). Thus, the near immediate availability of the "active lipid" in the claimed composition (e.g., Claims 96, 98-106, 114, 116, 117, and 119-125) is important to accomplishing the desired result in accordance with the claimed method (e.g., Claims 109-113 and 128-130).

In contrast, Pedersen *et al.* teaches a controlled release pharmaceutical formulation, which comprises a dry film coating (e.g., column 3, line 29) for preventing an active drug from being released all-at-once into the stomach. The film coating of Pedersen *et al.* is comprised, *inter alia*, of a hydrophobic substance (e.g., column 2, lines 39-50; column 3, lines 51-66), "which will result in the desired retardation of diffusion (in the present context, the term 'hydrophobic' indicates substances which, relative to water, have a contact angle of more than 90°)." (Pedersen *et al.*,

column 3, lines 53-57). Pedersen *et al.* particularly teach that the hydrophobic substance is selected from "hydrocarbons, waxes, oils and fats and mixtures thereof." (Pedersen *et al.*, column 3, line 67 through column 4, line 2). Pedersen *et al.* goes on to disclose "higher fatty acids" as examples of "wax-like substances" called for by the described controlled release coating formulation. In essence, Pedersen *et al.* teaches the use of a coating comprised of a waxy hydrophobic substance and a film-forming polymeric substance, which together act as a barrier to the immediate release of the active drug; instead, the drug is released along the entire GI tract including the colon.

The fatty acids in wax-like form taught by Pedersen *et al.*, however, would not qualify as "active lipids," as previously noted by Applicant in a response (mailed December 26, 2002) to the previous Office Action. The wax-like hydrophobic substances in the coating formulation of Pedersen *et al.* fail to "trigger the jejunal brake reflex," and are unlike active lipids "having a molecular structure similar to a hydrolyzed end-product of fat digestion," as recited in amended Claim 96 and 114.

Accordingly, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 102.

B. Rejections under 35 U.S.C. § 103(a)

To establish a prima facie case of obviousness, each of the following three criteria must be met. (MPEP 2143). First, the prior art references (or references when combined) must teach or suggest all the claim limitations. *In re Royka and Martin*, 490 F.2d 981, 180 USPQ 580, 583 (CCPA 1974). Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success, however, must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)(citing *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 [Fed. Cir. 1988]). The examiner bears

the burden of establishing a prima facie case of obviousness. *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (B.P.A.I. 1993).

The Examiner rejected Claims 96, 98-106, 114, 116-125, 137, and 138, under 35 U.S.C. § 103(a) as being unpatentable over Pedersen *et al.* The Examiner stated:

> **... Claims 96, 98-106, 114, 116, 117, 119-125, 137, and 138 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al. Pedersen is relied upon for the reason stated above. In the case that the applicant can overcome the above 102(b) rejection, it is the examiner's position that it would have been prima facie obvious for one of ordinary skill in the art to modify Pedersen's multi-unit controlled release composition with the expectation of at least similar result, since Pedersen teaches the advantageous result in the use of hydrophobic material to control the release rate of active substance throughout the GI tract.**
> **... Applicant argues that according to applicant's specification, "active lipid" encompasses "a digested or substantially digested molecule having a structure and function substantially similar to a hydrolyzed end-product of fat digestion, e.g. glycerol and fatty acids." However, the "wax-like substances" of Pedersen would not qualify as "active lipid", because at wax-like state, the fatty acids would not be considered fully hydrolyzed or "active". Contrary to the applicant's arguments, it is noted that the features upon which applicant relies on are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. The "wax-like substances" of Pedersen also include higher fatty acids such as myristic, palmitic, stearic, and behenic acids (column 4, lines 7-8), which is also use by applicant's invention as "active lipid" (applicant's attention is called to specification at page 12, 5th paragraph). Accordingly, such language suggests that Pedersen does teach a composition comprises "active-lipid".**
> **Applicant argues that the Examiner has not met the burden of establishing a prima facie case of obviousness, because Pedersen fails to teach or suggest the "active lipid". For the reasons stated above, it would have been obvious for one of ordinary skill in this art to, by routine experimentation select the hydrophobic substances, such as myristic, palmitic, stearic, and behenic acids, taught by Pedersen to obtain the claimed invention. Thus, the Examiner has met the burden of establishing a prima facie case of obviousness, because Pedersen does teach a controlled release composition comprises active lipid as claimed by the applicant.**
> **In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge**

gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In view of Applicant's amendments to Claims 96 and 114, as described above, the basis of rejection is overcome. Pedersen *et al.* fail to teach or suggest the claim element of an "active lipid", a limitation recited in each of the subject claims, *e.g.*, independent Claims 96 and 114 and the claims depending therefrom. As stated above in connection with Applicant's remarks relating to the Examiner's 35 U.S.C. § 102 rejection, the "active lipid" claimed in the present application is patentably distinct from the wax-like hydrophobic substance disclosed in Pedersen *et al.* The wax-like hydrophobic substances of Pedersen *et al.* fail to "trigger the jejunal brake reflex," and are unlike active lipids "having a molecular structure similar to a hydrolyzed end-product of fat digestion," as recited in amended Claim 96 and 114. Pedersen *et al.*, teach away from including such an element in their controlled release coating formulation, as the Pedersen *et al.* formulation relies on the fact that the film coating, including the waxy hydrophobic substance, remains intact after enteral delivery, rather than being in predigested or "active lipid" form.

In view of Applicant's amendments to independent Claims 96 and 114, the Examiner is respectfully requested to withdraw the rejection.

The Examiner also rejected Claims 96, 114, and 118, under 35 U.S.C. § 103(a) as being unpatentable over the combination of Pedersen *et al.* and U.S. Patent No. 5,411,751 granted to Crissinger *et al.* The Examiner stated:

... Claims 96, 114, and 118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen et al., and Crissinger et al. US 5,411,751. Pedersen is relied upon for the reasons stated above. Pedersen does not teach the additional of nutrient agent as claimed in claim 118.
Crissinger teaches the use of (C16-C22) fatty acid in food product to reduce GI irritation (abstract). The food product further comprises vitamins and minerals (column 3). Thus, it would have been obvious for one of ordinary skill in the art to prepare Pedersen's composition using the fatty acid in view of the teaching of Crissinger, because the references teach the advantageous result in the use of fatty acid. The expected result would be controlled release dosage form useful in pharmaceutical and/or food products.
... In response to applicant's argument that there is no suggestion to combine Pedersen et al. and Crissinger et al., the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is also noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Crissinger is relied upon solely for the teachings of additional nutrient agent. Crissinger teaches the use of fatty acid in an amount insufficient to damage the intestinal epithelium (columns 1-2).

In view of Applicant's amendment to independent Claims 96 and 114, as described above in connection with Applicant's remarks relating to the Examiner's 35 U.S.C. § 102 rejection, the "active lipid" claimed in the present application is patentably distinct from the wax-like hydrophobic substance disclosed in Pedersen *et al.* The wax-like hydrophobic substances of Pedersen *et al.* fail to "trigger the jejunal brake reflex," and are unlike active lipids "having a molecular structure similar to a hydrolyzed end-product of fat digestion," as recited in amended Claim 96 and 114. In light of the foregoing, one of ordinary skill in the art would lack motivation to combine the controlled release composition of Pedersen *et al.* with the infant formula of Crissinger *et al.* to arrive at the compositions recited in Claims 96, 114, and 118 of the present application.

For the foregoing reasons, the Examiner is respectfully requested to withdraw the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above remarks, it is submitted that this application is now ready for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney at (213) 896-6665.

Respectfully submitted,

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